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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,436	07/23/2002	Istvan Szelenyi	033285-009	6934

21839 7590 04/28/2004

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EXAMINER

COOK, REBECCA

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,436	SZELENYI ET AL.	
	Examiner	Art Unit	
	Rebecca Cook	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment to the specification overcomes the earlier objection under 37 CFR 1.71 and the rejection of claims 1-9 and 11 under 35 U.S.C. 112, first paragraph to written description.

Claim Rejections - 35 USC § 112

Claims 5-9 and 11 are again rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating rhinoconjunctivitis, does not reasonably provide enablement for treating all disorders of the lower and upper airway or treatment of all allergies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is no one treatment that is used for all of these disorders, which would include, but not be limited to, cancer; bacterial, viral and fungal infection; and black and brown lung disease. Applicants' intent to amend the claims to recite "allergic disorders" is noted, but said amendment does not appear in the amended claims of 10/28/03. Furthermore, said amendment would include anaphylactic reaction and allergic asthma, for which no support is seen in the specification.

Claims 6-9 and 11 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 6 and 9 it is not clear if the patient is required to have more than one disorder. Applicants argue that the specification and claims do not require that the

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patient have more than one disorder at one time. The claims should be amended to recite "A method for the treatment of one or more allergic disorders selected from allergic rhinitis and allergic conjunctivitis" to make this clear. This will also overcome the rejection under 35 U.S.C. 112, paragraph one.

Claims 7 and 8 do not further limit claim 5 from which they depend. Claim 5 recites intranasal or intraocular administration and claim 8 recites oral administration. If the intent is that said routes of administration are for the loteprednol then this should be made clear in the claims. Additionally, there is no support in claim 5 for the word "substance" in claim 7.

Applicants' intent to amend claims 1 and 4 to recite "pharmaceutically acceptable ester" is noted, but said amendment has not been made.

The remaining earlier rejections are withdrawn in view of the amendments to the claims.

It is noted that no effective amount is recited for the antihistamine in claims 1, 5, 9 and 11 or an effective amount of loteprednol in claim 11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedlaender for the reasons given in the Office Action of 7/28/03.

Applicants argue that Tables 1 and 2 of the specification show an overadditive effect in the combination of loteprednol and azelastine. This is not persuasive other than for claim 4 to the extent it reads on azelastine, since the data is not commensurate in scope with the claims.

Claims 1-9 and 11 are again rejected under 35 U.S.C. 103(a) as being unpatentable over EP 709 099 in view of WO 97/01337 for the reasons given in the Office Action of 8/28/03.

Applicants argue that EP 0 709 099 does not teach combining loteprednol with antihistamines. This is not persuasive, since it is cited to show that loteprednol is known in the art to treat allergic rhinitis. Similarly, WO 08/01377 is cited to show that it is known in the art to use antihistamines, including azelastine and levocabastine, to treat allergic rhinitis. The data in Tables 1 and 2 of the specification is persuasive only for the combination of loteprednol and azelastine, but is not persuasive other than for claim 4 to the extent it reads on azelastine, since the data is not commensurate in scope with the claims

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (571) 272-0584.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Pettus (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rebecca Cook

A handwritten signature in cursive script, appearing to read 'Rebecca Cook', written in black ink.

Primary Examiner
Art Unit 1614

April 26, 2004